

**REMARKS**

This responds to the Office Action dated July 27, 2005. In the Office Action, the Examiner rejected claims 1, 2, and 4, all of the claims pending in the application. Applicant respectfully requests reconsideration and reexamination in view of the following remarks.

The Examiner has rejected claims 1, 2, and 4 under 35 U.S.C. § 102 (a), alleging that the claims are anticipated by a 1986 publication by Bystryn, the applicant herein. In response, applicant notes that this issue was raised in prior applications in the copending chain by previous examiners. In U.S. Application Serial No. 07/485,780, the Examiner stated in an office action (copy thereof attached as Exhibit 1 hereto) that the subject reference became publicly available on May 5, 1986, and that although the predecessor application was filed on April 23, 1987, there were several authors on the article who were not named as inventors on the application. Applicant overcame this rejection by filing a declaration with the amendment filed in response to the Office Action. Applicant submits a copy of the declaration as Exhibit 2 hereto. Applicant submits that the foregoing rejection is overcome by the declaration, and respectfully submits that it may be withdrawn.

Next, the Examiner has lodged an statutory obviousness double patenting rejection, asserting that claimed invention herein would be obvious over the invention claimed in claim 1 of U.S. Patent No. 5,993,829; claims 1-2 and 4 of U.S. Patent No. 5,635,188; and claims 1-2, 4, and 10-11 of U.S. Patent No. 5,993,829. The Examiner asserts that although the cited claims are not identical, they are not patentably distinct from each

other because the claims of the instant invention encompass the same scope as that taught in the cited U.S. Patents. The Examiner suggests that a terminal disclaimer would overcome the double patenting rejection. Applicant submits herewith a terminal disclaimer, and requests that upon entry thereof, the rejection based upon obviousness double patenting be withdrawn.

Finally, the Examiner has rejected claims 1-2 and 4 under 35 U.S.C. § 103 (a), asserting that the claimed invention would have been obvious to a person of ordinary skill given the disclosures of Albino and Gupta. The Examiner asserts that Albino teaches the characterization of multiple melanoma associated surface antigens derived from multiple, different cell lines. The Examiner notes that although Albino does not teach culturing multiple different melanoma cell lines in a serum free media, Gupta teaches the purification of melanoma associated surface antigens from "spent" serum free media. The Examiner asserts that it would have been obvious to one of skill in the art at the time the invention was made to manufacture a polyvalent melanoma vaccine comprising multiple melanoma associated surface antigens derived from multiple cell lines cultured in serum free medium.

The Examiner further asserts that a person of ordinary skill in the art would have been motivated to do so because Albino taught that melanoma cell lines produce a diversity of surface antigens; Gupta taught that melanoma surface antigens are released from the surface of the melanoma cells and that these antigens could be purified in media free of serum proteins. The Examiner further contends that one of skill in the art would have been motivated to combine the references because the use of serum free media

provided for a means to isolate relatively purified population of melanoma associated surface antigens without contamination with serum proteins found in the culturing media containing serum. The Examiner also asserts that the use of multiple melanoma cell lines, as taught by Albino provides for diversity of melanoma antigens for which to generate a more diverse immune response. The Examiner concludes that one of ordinary skill would have a reasonable expectation of success in doing so because Gupta taught that the purification of melanoma surface antigen from serum free media would provide for an enriched population of surface antigen that was immunogenic.

Applicant respectfully traverses the foregoing obviousness rejection, and submits that the cited references, whether taken singly or in combination, do not render the claimed invention obvious. Neither of the cited references appears directed to treatment of melanoma; rather Gupta discusses development of a radioimmunoassay from tumor associated antigen isolated from spent culture medium of a single human melanoma cell line. The article appears to make no mention of use of the antigens to create a vaccine, much less how to make and use such a vaccine. Moreover, since Gupta is working with only one cell line, there is no way the Gupta article can be stretched to relate to the claimed vaccine, which involves antigens pooled from multiple different cell lines. Albino discusses antigens taken from multiple cell lines taken different metastases from the same patient, but again Albino seems interested in studying the morphology of these different antigens, and to make comparisons of the similarities and differences of the antigens taken from these different metastases within the same patient. He reports on phenotypic differences among the different cell lines, such as growth rate, morphology, pigmentation, and the expression of surface antigens and

glycoproteins. Albino likewise makes no mention of the possible use of the antigens that he obtained as a vaccine for the treatment of melanoma, nor does he appear to combine the antigens from the various cell lines to see if that act increases or decreases immune response.

Thus, it appears that the Examiner has taken two references involving melanoma antigens, and used the hindsight provided by the instant application to combine the references and fill in the considerable gaps in their respective discussions of melanoma. In the absence of hindsight, there would be no motivation to combine a reference discussing the morphology of several melanoma cell lines with a reference reporting on the design of a radioimmunoassay based upon antigens taken from a single melanoma cell line. Moreover, even if those references were combined, they would yield no clue concerning how to make or use a melanoma vaccine. Indeed, the references say so little about the immune response provoked by these antigens, that it cannot fairly said they even address the problem of how to treat melanoma, much less how to construct a usable vaccine for treating the disease. As such, applicant submits that the subject obviousness rejection is misplaced, and should be reconsidered and withdrawn.

In sum, applicant submits that he overcomes the anticipation rejection with the attached declaration and the double patenting rejection with the attached terminal disclaimer. Likewise, application has demonstrated why the pending obviousness rejection is incorrect, and should be withdrawn. Notice of allowability of the pending claims is respectfully requested.

Applicant: Jean-Claude Bystryn  
U.S. Serial No.: 10/046,880  
Filing Date: January 15, 2002  
Page 6

The Commissioner is hereby authorized to charge any fee related to the filing of this response to deposit account no. 03-3125. In addition, if any further extension is required to file or consider this response, applicant hereby requests such extension, and authorizes the fee therefor to be charged to the foregoing deposit account.

Dated: November 28, 2005

By: 

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

Commissioner for Patents, P.O. Box 1450,  
Alexandria, VA 22313-1450

Robert D. Katz  
Reg. No. 30,141

Date

Robert D. Katz  
Reg. No. 30,141  
c/o Cooper & Dunham LLP  
1185 Avenue of the Americas  
New York, New York 10036  
Tel. (212) 278-0400  
Fax (212) 391-0525  
Email [rkatz@cooperdunham.com](mailto:rkatz@cooperdunham.com)

Attorney for Applicant(s)